October 2005

# Arizona State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

4425 W Olive Ave, Suite 140, Glendale, AZ 85302-3844
Web site: www.pharmacy.state.az.us
E-mail: info@azsbp.com

## New Board Member Appointed

On August 10, 2005, Governor Janet Napolitano appointed Zina S. Berry, PharmD, to a five-year term on the Arizona State Board of Pharmacy. Dr Berry is a graduate of the University of Arizona College of Pharmacy and is a certified geriatric pharmacist. She has experience in long-term care pharmacy and home infusion pharmacy. She is currently employed at Walgreen's Home Care pharmacy. The Board staff looks forward to working with Dr Berry. A new pharmacy technician is expected to be appointed soon.

## Precursor Chemicals (Pseudoephedrine): Legislation Takes Effect October 31, 2005

Senate Bill 1473 will take effect October 31, 2005. On that date, the possession, purchase, and sale of pseudoephedrine will be further restricted in Arizona. The amount of pseudoephedrine that a person can purchase without a valid prescription will be reduced from 24 grams to 9 grams (three 3-gram packages). The exemption allowing a person to sell a precursor chemical if the transaction involves cash or money order in an amount less than $500 is deleted. All non-prescription retailer permittees under the Board of Pharmacy are required to keep all products in which pseudoephedrine is the single active ingredient behind a store counter or in a locked facility inaccessible to customers without the assistance of store personnel. Liquid, liquid capsule, or gel capsule forms are exempt, and violations are designated a Class 2 Misdemeanor.

## USP 797 Task Force

A task force of community, nuclear and hospital practitioners, and other interested parties recently spent considerable time reviewing the sterile products regulations in an attempt to incorporate practical applications of various recommendations contained in United States Pharmacopeia General Chapter 797 Pharmaceutical Compounding - Sterile Preparations. Check the Board's Web site for more updates on this issue in coming months.

## Board Web Site Revised to Comply with State Template

The Board's Web site has been revised to comply with the state of Arizona template for official state Web sites. A privacy policy and state required links have been added. The address is still www.pharmacy.state.az.us. The Web site has all of the same features and content in a "horizontal" format with "drop-down" menus rather than the vertical style previously used. Please e-mail info@azsbp.com if there are features you notice missing or would like features added to the Web site.

## License and Permit Renewals Began September 15, 2005

License and permit renewal letters were mailed out in early September, and online renewals are available as a pilot for pharmacist renewals from September 15 to November 15, 2005. An insert was mailed with the renewal letters detailing the process. Pharmacists have been instructed to visit the Web site identified in the mailed insert, enter his or her license number and birth date, answer a few questions, and certify that he or she is in compliance with continuing education requirements. The Web site accepts VISA®, MasterCard®, American Express®, or Discover® cards; a printable receipt will be available. Technicians and permittees (pharmacies, wholesalers, etc) will be added to the program next year if all goes well with the pilot this year.

## New Wholesale Permit Requirements

Full-service (prescription-only) wholesalers who renew in September and October this year will be subject to the provisions of House Bill 2193 and the new statutes created as a result of the Bill's passage. The statutes are A.R.S. §32-1981 Definitions; 32-1982 Full-service wholesale permitees; bonds; designated representatives; application; 32-1983 Restrictions on transactions; 32-1984 Pedigrees; electronic files; and 32-1985 Injunctive relief.

All full-service wholesalers will be required to provide a $100,000 bond to renew a full-service wholesale permit as well as name a designated representative for each permit. A pedigree will be required for each drug product that leaves the normal distribution channel. Violations of the new statutes may be classified as a Class 2 Felony. Please review the statutes and definitions before calling the Board office. They are available on our Web site at www.pharmacy.state.az.us/pharmacyact.html, under the selection "Arizona Revised Statutes: Pharmacy Act, Chapter 18, Title 32."

## Fraudulent Prescriptions and Department of Public Safety

The Department of Public Safety (DPS) regularly receives notices from pharmacies, usually through FAX NET 1®, regard-

*Continued on page 4*

## DEA Amends Rule for Reports of Theft or Significant Loss of Controlled Substances

Drug Enforcement Administration's (DEA) amended regulations regarding reports by registrants of theft or significant loss of controlled substances became effective September 12, 2005. Changes were made to the regulations, found in Title 21 of the Code of Federal Regulations, Part 1300 to 1399, due to confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. Specifically, DEA made changes in order to clarify the exact meaning of the phrases "upon discovery" and "significant loss."

Regarding the timing of initial theft or loss reports, DEA inserted the word "immediately" before the phrase "upon discovery." While DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, he or she should provide, in writing, initial notification of the event. This notification may be a short statement provided by fax. DEA notes that faxing is not the only method a registrant may use, but that the notification should be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA.

To help registrants determine whether or not a loss is "significant," DEA has added to the rule a list of factors to be considered. DEA recognizes that no single objective standard can be applied to all registrants – what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. If a registrant is in doubt as to whether or not the loss is significant, DEA advises the registrant to err on the side of caution in alerting the appropriate law enforcement authorities.

Regarding "in-transit losses of controlled substance," DEA intends that all in-transit losses be reported, not just significant losses; therefore, the text is being amended to reflect this.

Changes to the regulations were reported in the August 12, 2005 edition of the *Federal Register*.

## FDA Releases Update on Combating Counterfeit Drugs

Food and Drug Administration (FDA) recently released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (Update)." This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard setting bodies, State and Federal agencies, international governmental entities, and others to advance the measures outlined in the 2004 report such as the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of the product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

## "Fax noise" = Medication Errors in the making

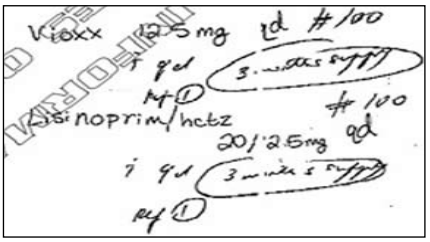
*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Suite 810, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

**Problem**: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater number of clarification calls than those received by other methods of communication.[1] ISMP received a report from a long-term care facility about a patient who had been

receiving **Neurontin**® (gabapentin) 600 mg TID [three times a day]. However, an order had been faxed to the pharmacy to change the Neurontin dose to "**300 mg** 1 tab QID [four times a day]." The change was made and the new dose was sent to the facility. Later, when the pharmacist received the original order from the long-term care facility and compared it with the faxed copy, he realized that the physician had actually requested a change to "**800 mg** 1 tab QID." The left side of the order had been cut off during the fax transmission, making the "8" look like a "3." Fortunately, since the pharmacist had been sent the original order for comparison, he quickly realized the mistake. Unfortunately, not all pharmacies receive the original prescription for comparison purposes.

In another report received by ISMP, a faxed prescription was received at a pharmacy for what appeared to be **Monopril**® (fosinopril) **10 mg** #90 one tablet daily. Despite the fact that the fax machine created a definite vertical streak that ran between the drug name and the strength, the pharmacist felt confident in her interpretation of the prescription. Unfortunately, it was later discovered that the prescription was actually for **40 mg**. The streak had run through the "4" in 40 mg, making it look like 10 mg instead.

The following prescription (see image below) was faxed to a mail-order pharmacy. Look at the bottom order for "Lisinopril/hctz." (Note: ISMP does not condone the use of the abbreviation "hctz.") The pharmacist interpreted this order as "20/25 mg." But what the prescriber had actually written was "20/12.5 mg." A subtle vertical gap in the faxed copy (which can be seen "breaking" the circles around "3 months supply") had obliterated the "1" in 12.5. In addition, the pharmacist reading the order had misinterpreted the decimal point as one of many stray marks on the faxed prescription.




**Safe Practice Recommendations**: "Fax noise" (the random marks and streaks on faxes) is an inherent problem with this form of communication, which may be more common in old or poorly maintained fax machines. Usually, fax noise is just an inconvenience. In the case of prescriptions, however, there is a very real chance that a patient could be harmed by misinterpretations caused by fax noise. To manage this risk, safeguards should be instilled into the fax process. Such safeguards include a careful review of all prescriptions received by fax for fax noise. If the transmission has fax noise in the area of the order, the prescriber should be contacted to confirm the prescription. Whenever possible, compare the faxed order against the original prescription. Prescribers should consider giving a copy of the prescription to the patient to present at the pharmacy for verification. To prevent confusion or duplication of the prescription at a different pharmacy, the copy could be stamped with a statement such as "Verification Copy ONLY" to indicate that the prescription was already faxed to a particular pharmacy. Maintenance should be regularly scheduled for fax machines on both the sending and receiving end. If maintenance fails to improve fax quality, the machine should be replaced.

[1.] Feifer RA et al. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *JMCP* 2003;9:346-352.

## December 2005 FPGEE Date and Locations Announced

On December 3, 2005, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Francisco, CA. Candidates who have been accepted to sit for the December 3, 2005 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE®, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

## 2006 Survey of Pharmacy Law

NABP's *2006 Survey of Pharmacy Law* CD-ROM will be available in late November 2005. New topics include the number of wholesale drug distributors and laws and/or regulations concerning the sales of over-the-counter pseudoephedrine, and information concerning emergency contraception.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. Most charts specify terms that can be used when conducting searches on NABP's NABPLAW® Online state pharmacy law and rules database. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

*Continued from page 1*

ing suspicious or fraudulent prescriptions. DPS no longer has a unit dedicated to the investigation of prescription fraud and abuse so these notices are no longer necessary. Reports of such crimes should be made to the local city police or county sheriff as appropriate, and any other notifications that may be required by law or rule. Notification to DPS is not necessary. Please note that this does not change the reporting requirements under A.R.S. §13-3404 regarding the sale of precursor or regulated chemicals. Those requirements remain unchanged.

## *Disciplinary Actions – Board of Pharmacy (Actions Since July 2005* Newsletter*)*

*Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).*

**James Edwards, Technician Trainee** – License suspended for 30 days followed by a one-year probation; civil penalty of $250. Theft of drugs and merchandise from a pharmacy.

**Lori Wickenhauser, RPh** – License suspended for 10 days, followed by a five-year probation and the Pharmacists Assisting Pharmacists in Arizona (PAPA) substance abuse contract; Controlled Substance violations, substance abuse.

**excelleRx Pharmacy** – Permit censured and shall be required to submit to two additional pharmacy inspections within the next 12 months and shall pay the costs of these inspections.

**Paul Dahlk, RPh** – License suspended for a period of time to be determined by the steering committee of the PAPA, for a minimum of six months, but not more than one year, followed by a probation for a minimum four years, but not more than four and one-half years. Concurrent five-year PAPA contract.

**Daniel Osborn, RPh** – License suspended for 15 days, effective on the date of this Order, followed by probation for one year; Civil penalty of $1,300.

**Jonathan Venier, RPh** – License on probation for five years, concurrent PAPA substance abuse contract: Controlled Substance violations.

**Imelda Sedano**, **Pharmacy Technician** – License revoked, Controlled Substance violations.

**Scott Huft, RPh** – License suspended for six months to one year, followed by five-year probation and PAPA substance abuse contract: Controlled Substance violations.

## *Disciplinary Actions – Other Health Care Practitioner Boards*

*Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).*

**Alok Sinha, DO (#3347)** – Interim Order for Summary Suspension, effective July 15, 2005.

**Michael L. Berman, DO (#3432)** – Unrestricted License and Reinstatement, effective May 7, 2005.

**Steve J. Locknikar, DO (#2669)** – Suspended for not more than one year, followed by five years probation, effective May 25, 2005.

**Jacqueline S. Silkey, MD (#26842)** – Decree of censure, and five years probation, effective June 9, 2005.

**Susan Van Dyke, MD (#20156)** – Voluntary inactivation, effective May 20, 2005.

**Gary S. Blass, MD (#22064)** – Revoked, effective June 14, 2005.

**Gerald W. Rounsborg, MD (#8162) –** Voluntary surrender of license, effective August 12, 2005.

**William J. Casey, Jr, MD (**# 9866 ) – Voluntary surrender of license, effective August 12, 2005.

**Deborah S. Golub, MD (**#31682) – Decree of Censure, five years probation, 20 additional hours of continuing medical education, effective May 11, 2005.



The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Harlan "Hal" Wand, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

ARIZONA STATE BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744